

112TH CONGRESS  
1ST SESSION

# H. R. 1311

To provide for the coverage of medically necessary food under Federal health programs and private health insurance.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 1, 2011

Ms. BALDWIN (for herself, Mr. POLIS, Ms. JACKSON LEE of Texas, Ms. EDDIE BERNICE JOHNSON of Texas, and Mr. JOHNSON of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Armed Services, and Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To provide for the coverage of medically necessary food under Federal health programs and private health insurance.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Foods Equity  
5 Act of 2011”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) Newborns are screened for inborn errors of  
2 metabolism, but treatment for such conditions is not  
3 uniformly covered by insurance.

4 (2) Each year approximately 2,550 children in  
5 the United States are diagnosed with an inborn  
6 error of metabolism disorder, requiring foods modi-  
7 fied to be void of the nutrient or nutrients the  
8 child's body is incapable of processing, or requiring  
9 supplementation with vitamins or amino acids.

10 (3) More than 35 States have passed laws to at  
11 least partially address the inequity in coverage for  
12 medically necessary foods, critical treatment for such  
13 disorders.

14 (4) The cost associated with providing medically  
15 necessary foods presents a large financial burden for  
16 many families.

17 (5) There is no current cure for inborn errors  
18 of metabolism disorders and treatment is necessary  
19 during the entire lifespan of the individual.

20 **SEC. 3. COVERAGE IN FEDERAL HEALTH PROGRAMS OF**  
21 **MEDICALLY NECESSARY FOOD AND FOOD**  
22 **MODIFIED TO BE LOW PROTEIN.**

23 (a) COVERAGE UNDER THE MEDICARE PROGRAM.—

1           (1) COVERAGE OF MEDICALLY NECESSARY  
2       FOOD UNDER THE ORIGINAL MEDICARE FEE-FOR-  
3       SERVICE PROGRAM.—

4           (A) IN GENERAL.—Section 1861(s)(2) of  
5       the Social Security Act (42 U.S.C. 1395x(s)(2))  
6       is amended—

7           (i) in subparagraph (EE), by striking  
8       “and” at the end;

9           (ii) in subparagraph (FF), by insert-  
10      ing “and” at the end; and

11          (iii) by adding at the end the fol-  
12      lowing new subparagraph:

13          “(GG) medically necessary food (as defined in  
14      subsection (iii)) and food modified to be low protein  
15      that is formulated to be consumed or administered  
16      under the supervision of a qualified medical pro-  
17      vider, for the treatment of conditions as rec-  
18      ommended by the Advisory Committee on Heritable  
19      Disorders in Newborns and Children, and the med-  
20      ical equipment and supplies necessary to administer  
21      such food;”.

22          (B) DEFINITION.—Section 1861 of the So-  
23      cial Security Act (42 U.S.C. 1395x) is amended  
24      by adding at the end the following new sub-  
25      section:

1 “(iii)(1) The term ‘medically necessary food’—

2 “(A) means a food which is formulated to be  
3 consumed or administered enterally under the super-  
4 vision of a physician and which is intended for the  
5 specific dietary management of a disease or condi-  
6 tion for which distinctive nutritional requirements,  
7 based on recognized scientific principles, are estab-  
8 lished by medical evaluation; and

9 “(B) includes nutritionally modified counter-  
10 parts of traditional foods and other forms of foods  
11 such as formulas, pills, capsules, and bars, so long  
12 as consumed or administered enterally.

13 “(2) For purposes of paragraph (1), the term  
14 ‘enterally’ refers to consumption or administration  
15 through the gastrointestinal tract, whether orally or by  
16 tube.”.

17 (C) PAYMENT.—Section 1833(a)(1) of the  
18 Social Security Act (42 U.S.C. 1395l(a)(1)) is  
19 amended—

20 (i) by striking “and” before “(Z)”;

21 and

22 (ii) by inserting before the semicolon  
23 at the end the following: “, and (AA) with  
24 respect to medically necessary food and  
25 pharmacological doses of vitamins and

amino acids under section 1861(s)(2)(GG),  
the amounts paid shall be 80 percent of  
the lesser of the actual charge for the serv-  
ices or 85 percent of the amount deter-  
mined under the fee schedule established  
under section 1848(b) for the same serv-  
ices if furnished by a physician”.

(2) INCLUSION OF PHARMACOLOGICAL DOSES  
OF VITAMINS AND AMINO ACIDS AS A COVERED PART  
D DRUG.—

(A) IN GENERAL.—Section 1860D–2(e)(1)  
of the Social Security Act (42 U.S.C. 1395w–  
102(e)(1)) is amended—

(i) in subparagraph (A), by striking  
“or” at the end;

(ii) in subparagraph (B), by striking  
the comma at the end and inserting “; or”;  
and

(iii) by inserting after subparagraph  
(B) the following new subparagraph:

“(C) pharmacological doses of vitamins  
and amino acids used for the treatment of in-  
born errors of metabolism, for the treatment of  
conditions as recommended by the Advisory  
Committee on Heritable Disorders in Newborns

1 and Children and as prescribed by a qualified  
2 medical provider,”.

3 (B) EFFECTIVE DATE.—The amendments  
4 made by subparagraph (A) shall apply to plan  
5 years beginning on or after the date that is 6  
6 months after date of enactment of this Act.

7 (b) COVERAGE UNDER THE MEDICAID PROGRAM.—

8 (1) IN GENERAL.—Section 1905 of the Social  
9 Security Act (42 U.S.C. 1396d) is amended—

10 (A) in subsection (a)—

11 (i) in paragraph (12), by inserting  
12 “including pharmacological doses of vita-  
13 mins and amino acids used for the treat-  
14 ment of inborn errors of metabolism, for  
15 the treatment of conditions as rec-  
16 ommended by the Advisory Committee on  
17 Heritable Disorders in Newborns and Chil-  
18 dren and as prescribed by a qualified med-  
19 ical provider,” after “prescribed drugs,”;

20 (ii) in paragraph (28), by striking  
21 “and” at the end;

22 (iii) in paragraph (29), by striking the  
23 comma at the end and inserting “; and”;  
24 and

1 (iv) by inserting after paragraph (29)  
2 the following new paragraph:

3 “(30) medically necessary food (as defined in  
4 subsection (ee)) and food modified to be low protein  
5 that is formulated to be consumed or administered  
6 under the supervision of a qualified medical pro-  
7 vider, for the treatment of conditions as rec-  
8 ommended by the Advisory Committee on Heritable  
9 Disorders in Newborns and Children, and the med-  
10 ical equipment and supplies necessary to administer  
11 such food,”; and

12 (B) by adding at the end the following new  
13 subsection:

14 “(ee) MEDICALLY NECESSARY FOOD DEFINED.—

15 “(1) IN GENERAL.—For purposes of subsection  
16 (a)(30), the term ‘medically necessary food’—

17 “(A) means a food which is formulated to  
18 be consumed or administered enterally under  
19 the supervision of a physician and which is in-  
20 tended for the specific dietary management of  
21 a disease or condition for which distinctive nu-  
22 tritional requirements, based on recognized sci-  
23 entific principles, are established by medical  
24 evaluation; and

1           “(B) includes nutritionally modified coun-  
2           terparts of traditional foods and other forms of  
3           foods such as formulas, pills, capsules, and  
4           bars, so long as consumed or administered  
5           enterally.

6           “(2) ENTERALLY.—For purposes of paragraph  
7           (1), the term ‘enterally’ refers to consumption or ad-  
8           ministration through the gastrointestinal tract,  
9           whether orally or by tube.”.

10          (2) EXCEPTION TO REBATE EXCLUSION.—Sec-  
11          tion 1927(d)(2)(E) of the Social Security Act (42  
12          U.S.C. 1396r–8(d)(2)(E)) is amended by inserting  
13          “, pharmacological doses of vitamins and amino  
14          acids used for the treatment of inborn errors of me-  
15          tabolism, for the treatment of conditions as rec-  
16          ommended by the Advisory Committee on Heritable  
17          Disorders in Newborns and Children and as pre-  
18          scribed by a qualified medical provider,” after “pre-  
19          natal vitamins”.

20          (3) CONFORMING AMENDMENT.—Section  
21          1902(a)(10)(A) of the Social Security Act (42  
22          U.S.C. 1396a(a)(10)(A)) is amended, in the matter  
23          preceding clause (i), by striking “and (28)” and in-  
24          serting “(28), and (30)”.



1           (4) EXCEPTION TO EFFECTIVE DATE IF STATE  
2       LEGISLATION REQUIRED.—In the case of a State  
3       plan for medical assistance under title XIX of the  
4       Social Security Act which the Secretary of Health  
5       and Human Services (referred to in this Act as the  
6       “Secretary”) determines requires State legislation  
7       (other than legislation appropriating funds) in order  
8       for the plan to meet the additional requirement im-  
9       posed by the amendments made by this subsection,  
10      the State plan shall not be regarded as failing to  
11      comply with the requirements of such title solely on  
12      the basis of its failure to meet this additional re-  
13      quirement before the first day of the first calendar  
14      quarter beginning after the close of the first regular  
15      session of the State legislature that begins after the  
16      date of the enactment of this Act. For purposes of  
17      the previous sentence, in the case of a State that has  
18      a 2-year legislative session, each year of such session  
19      shall be deemed to be a separate regular session of  
20      the State legislature.

21      (c) COVERAGE UNDER CHIP.—

22           (1) IN GENERAL.—

23           (A) MEDICALLY NECESSARY FOOD.—Sec-  
24      tion 2103(c) of the Social Security Act (42

1 U.S.C. 1397cc(c)) is amended by adding at the  
2 end the following:

3 “(9) MEDICALLY NECESSARY FOOD.—

4 “(A) IN GENERAL.—The child health as-  
5 sistance provided to a targeted low-income child  
6 under the plan shall include coverage of medi-  
7 cally necessary food and food modified to be low  
8 protein that is formulated to be consumed or  
9 administered under the supervision of a quali-  
10 fied medical provider, for the treatment of con-  
11 ditions as recommended by the Advisory Com-  
12 mittee on Heritable Disorders in Newborns and  
13 Children, and the medical equipment and sup-  
14 plies necessary to administer such food.

15 “(B) DEFINITIONS.—In this paragraph—

16 “(i) the term ‘medically necessary  
17 food’—

18 “(I) means a food which is for-  
19 mulated to be consumed or adminis-  
20 tered enterally under the supervision  
21 of a physician and which is intended  
22 for the specific dietary management of  
23 a disease or condition for which dis-  
24 tinctive nutritional requirements,  
25 based on recognized scientific prin-

1 principles, are established by medical eval-  
2 uation; and

3 “(II) includes nutritionally modi-  
4 fied counterparts of traditional foods  
5 and other forms of foods such as for-  
6 mulas, pills, capsules, and bars, so  
7 long as consumed or administered  
8 enterally; and

9 “(ii) the term ‘enterally’ refers to con-  
10 sumption or administration through the  
11 gastrointestinal tract, whether orally or by  
12 tube.”.

13 (B) VITAMINS AND AMINO ACIDS.—Section  
14 2110(a)(6) of the Social Security Act (42  
15 U.S.C. 1397jj(a)(6)) is amended by striking  
16 “and biologicals and the administration of such  
17 drugs and biologicals, only if such drugs and  
18 biologicals” and inserting “, pharmacological  
19 doses of vitamins and amino acids used for the  
20 treatment of inborn errors of metabolism, for  
21 the treatment of conditions as recommended by  
22 the Advisory Committee on Heritable Disorders  
23 in Newborns and Children and as prescribed by  
24 a qualified medical provider, and biologicals,  
25 and the administration of such drugs, vitamins

1           and amino acids, and biologicals, only if such  
2           drugs, vitamins and amino acids, and  
3           biologicals”.

4           (2) CONFORMING AMENDMENT.—Section  
5           2103(a) of the Social Security Act (42 U.S.C.  
6           1397cc(a)) is amended, in the matter preceding  
7           paragraph (1), by striking “, and (7)” and inserting  
8           “, (7), and (9)”.

9           (d) AVAILABILITY OF MEDICALLY NECESSARY FOOD,  
10          FOOD MODIFIED TO BE LOW PROTEIN, AND RELATED  
11          ITEMS UNDER THE TRICARE PROGRAM.—Section  
12          1077(a)(8) of title 10, United States Code, is amended  
13          by striking “including” and all that follows and inserting  
14          “including the following:

15                 “(A) Well-baby care that includes one  
16                 screening of an infant for the level of lead in  
17                 the blood of the infant.

18                 “(B) Medically necessary food (as defined  
19                 in section 1861(iii) of the Social Security Act)  
20                 and food modified to be low protein that is for-  
21                 mulated to be consumed or administered under  
22                 the supervision of a qualified medical provider,  
23                 for the treatment of conditions as recommended  
24                 by the Advisory Committee on Heritable Dis-  
25                 orders in Newborns and Children, and the med-

1           ical equipment and supplies necessary to admin-  
2           ister such food.

3           “(C) Pharmacological doses of vitamins  
4           and amino acids used for the treatment of in-  
5           born errors of metabolism and other conditions  
6           as recommended by the Advisory Committee on  
7           Heritable Disorders in Newborns and Chil-  
8           dren.”.

9   **SEC. 4. COVERAGE IN THE PRIVATE INSURANCE MARKET**  
10                   **OF MEDICALLY NECESSARY FOOD AND FOOD**  
11                   **MODIFIED TO BE LOW PROTEIN.**

12       (a) GROUP HEALTH PLANS.—

13           (1) AMENDMENTS TO ERISA.—

14               (A) IN GENERAL.—Subpart B of part 7 of  
15           title I of the Employee Retirement Income Se-  
16           curity Act of 1974 (29 U.S.C. 1185 et seq.) is  
17           amended by adding at the end the following:

18   **“SEC. 716. COVERAGE OF MEDICALLY NECESSARY FOOD**  
19                   **AND FOOD MODIFIED TO BE LOW PROTEIN.**

20       “(a) DEFINITION.—In this section—

21           “(1) the term ‘medically necessary food’—

22               “(A) means a food which is formulated to  
23           be consumed or administered enterally under  
24           the supervision of a physician and which is in-  
25           tended for the specific dietary management of

1 a disease or condition for which distinctive nu-  
2 tritional requirements, based on recognized sci-  
3 entific principles, are established by medical  
4 evaluation; and

5 “(B) includes nutritionally modified coun-  
6 terparts of traditional foods and other forms of  
7 foods such as formulas, pills, capsules, and  
8 bars, so long as consumed or administered  
9 enterally; and

10 “(2) the term ‘enterally’ refers to consumption  
11 or administration through the gastrointestinal tract,  
12 whether orally or by tube.

13 “(b) COVERAGE.—

14 “(1) MEDICALLY NECESSARY FOOD AND FOOD  
15 MODIFIED TO BE LOW PROTEIN.—A group health  
16 plan, or a health insurance issuer that provides  
17 health insurance coverage in connection with a group  
18 health plan, shall provide coverage for medically nec-  
19 essary food and food modified to be low protein that  
20 is formulated to be consumed or administered under  
21 the supervision of a qualified medical provider, for  
22 the treatment of conditions as recommended by the  
23 Advisory Committee on Heritable Disorders in  
24 Newborns and Children, and the medical equipment  
25 and supplies necessary to administer such food.

1           “(2) VITAMINS AND AMINO ACIDS.—A group  
 2           health plan, or a health insurance issuer that pro-  
 3           vides health insurance coverage in connection with a  
 4           group health plan, that provides prescription drug  
 5           coverage shall provide coverage for pharmacological  
 6           doses of vitamins and amino acids used for the  
 7           treatment of inborn errors of metabolism, for the  
 8           treatment of conditions as recommended by the Ad-  
 9           visory Committee on Heritable Disorders in  
 10          Newborns and Children and as prescribed by a  
 11          qualified medical provider, to the same extent as  
 12          other prescription drug coverage under such plan or  
 13          coverage.”.

14                   (B) CONFORMING AMENDMENT.—The  
 15                  table of contents in section 1 of such Act is  
 16                  amended by inserting after the item relating to  
 17                  section 714 the following new items:

“Sec. 715. Additional market reforms.

“Sec. 716. Coverage of medically necessary food and food modified to be low  
 protein.”.

18                   (2) AMENDMENTS TO THE PUBLIC HEALTH  
 19                  SERVICE ACT.—Subpart 2 of part A of title XXVII  
 20                  of the Public Health Service Act (42 U.S.C. 300gg–  
 21                  4 et seq.) is amended by adding at the end the fol-  
 22                  lowing new section:

1 **“SEC. 2729. COVERAGE OF MEDICALLY NECESSARY FOOD**  
2 **AND FOOD MODIFIED TO BE LOW PROTEIN.**

3 “(a) DEFINITIONS.—In this section—

4 “(1) the term ‘medically necessary food’—

5 “(A) means a food which is formulated to  
6 be consumed or administered enterally under  
7 the supervision of a physician and which is in-  
8 tended for the specific dietary management of  
9 a disease or condition for which distinctive nu-  
10 tritional requirements, based on recognized sci-  
11 entific principles, are established by medical  
12 evaluation; and

13 “(B) includes nutritionally modified coun-  
14 terparts of traditional foods and other forms of  
15 foods such as formulas, pills, capsules, and  
16 bars, so long as consumed or administered  
17 enterally; and

18 “(2) the term ‘enterally’ refers to consumption  
19 or administration through the gastrointestinal tract,  
20 whether orally or by tube.

21 “(b) COVERAGE.—

22 “(1) MEDICALLY NECESSARY FOOD AND FOOD  
23 MODIFIED TO BE LOW PROTEIN.—A group health  
24 plan, or a health insurance issuer that provides  
25 health insurance coverage in connection with a group  
26 health plan, shall provide coverage for medically nec-



1       essary food and food modified to be low protein that  
 2       is formulated to be consumed or administered under  
 3       the supervision of a qualified medical provider, for  
 4       the treatment of conditions as recommended by the  
 5       Advisory Committee on Heritable Disorders in  
 6       Newborns and Children, and the medical equipment  
 7       and supplies necessary to administer such food.

8               “(2) VITAMINS AND AMINO ACIDS.—A group  
 9       health plan, or a health insurance issuer that pro-  
 10      vides health insurance coverage in connection with a  
 11      group health plan, that provides prescription drug  
 12      coverage, shall provide coverage for pharmacological  
 13      doses of vitamins and amino acids used for the  
 14      treatment of inborn errors of metabolism, for the  
 15      treatment of conditions as recommended by the Ad-  
 16      visory Committee on Heritable Disorders in  
 17      Newborns and Children and as prescribed by a  
 18      qualified medical provider, to the same extent as  
 19      other prescription drug coverage under such plan or  
 20      coverage.”.

21               (3) AMENDMENTS TO THE INTERNAL REVENUE  
 22      CODE.—

23                       (A) IN GENERAL.—Subchapter B of chap-  
 24                      ter 100 of the Internal Revenue Code of 1986  
 25                      (relating to other group health plan require-

1           ments) is amended by inserting after section  
2           9813 the following new section:

3   **“SEC. 9814. COVERAGE OF MEDICALLY NECESSARY FOOD**  
4           **AND FOOD MODIFIED TO BE LOW PROTEIN.**

5           “(a) DEFINITIONS.—In this section—

6                   “(1) the term ‘medically necessary food’—

7                           “(A) means a food which is formulated to  
8                   be consumed or administered enterally under  
9                   the supervision of a physician and which is in-  
10                  tended for the specific dietary management of  
11                  a disease or condition for which distinctive nu-  
12                  tritional requirements, based on recognized sci-  
13                  entific principles, are established by medical  
14                  evaluation; and

15                   “(B) includes nutritionally modified coun-  
16                  terparts of traditional foods and other forms of  
17                  foods such as formulas, pills, capsules, and  
18                  bars, so long as consumed or administered  
19                  enterally; and

20                   “(2) the term ‘enterally’ refers to consumption  
21                  or administration through the gastrointestinal tract,  
22                  whether orally or by tube.

23           “(b) COVERAGE.—

24                   “(1) MEDICALLY NECESSARY FOOD AND FOOD  
25                  MODIFIED TO BE LOW PROTEIN.—A group health

1 plan, or a health insurance issuer that provides  
2 health insurance coverage in connection with a group  
3 health plan, shall provide coverage for necessary  
4 medically necessary food and food modified to be low  
5 protein that is formulated to be consumed or admin-  
6 istered under the supervision of a qualified medical  
7 provider, for the treatment of conditions as rec-  
8 ommended by the Advisory Committee on Heritable  
9 Disorders in Newborns and Children, and the med-  
10 ical equipment and supplies necessary to administer  
11 such food.

12 “(2) VITAMINS AND AMINO ACIDS.—A group  
13 health plan, or a health insurance issuer that pro-  
14 vides health insurance coverage in connection with a  
15 group health plan, that provides prescription drug  
16 coverage, shall provide coverage for pharmacological  
17 doses of vitamins and amino acids used for the  
18 treatment of inborn errors of metabolism, for the  
19 treatment of conditions as recommended by the Ad-  
20 visory Committee on Heritable Disorders in  
21 Newborns and Children and as prescribed by a  
22 qualified medical provider, to the same extent as  
23 other prescription drug coverage under such plan or  
24 coverage.”.

1 (B) CONFORMING AMENDMENT.—The  
 2 table of sections for subchapter B of chapter  
 3 100 of such Code is amended by inserting after  
 4 the item relating to section 9813 the following  
 5 new item:

“Sec. 9814. Coverage of medically necessary food and food modified to be low protein.”.

6 (b) INDIVIDUAL MARKET.—Subpart 2 of part B of  
 7 title XXVII of the Public Health Service Act (42 U.S.C.  
 8 300gg–51 et seq.) is amended by adding at the end the  
 9 following new section:

10 **“SEC. 2754. COVERAGE OF MEDICALLY NECESSARY FOOD**  
 11 **AND FOOD MODIFIED TO BE LOW PROTEIN.**

12 “The provisions of section 2729 shall apply to health  
 13 insurance coverage offered by a health insurance issuer  
 14 in the individual market in the same manner as they apply  
 15 to health insurance coverage offered by a health insurance  
 16 issuer in connection with a group health plan in the small  
 17 or large group market.”.

18 (c) AMENDMENT TO PPACA.—Section 1302(b)(1) of  
 19 the Patient Protection and Affordable Care Act (42  
 20 U.S.C. 18022(b)(1)) is amended by adding at the end the  
 21 following:

22 “(K) Medically necessary food, as defined  
 23 in section 2729 of the Public Health Service  
 24 Act.”.

1 **SEC. 5. EFFECTIVE DATE; DETERMINATION OF MINIMUM**  
2 **YEARLY COVERAGE.**

3 (a) **EFFECTIVE DATE.**—The amendments made by  
4 sections 3 and 4 shall apply to plan years beginning after  
5 the date that is 180 days after the date of enactment of  
6 this Act.

7 (b) **DETERMINATION BY SECRETARY.**—

8 (1) **IN GENERAL.**—Prior to the date described  
9 under subsection (a), the Secretary of Health and  
10 Human Services (referred to in this Act as the “Sec-  
11 retary”) shall determine the minimum yearly cov-  
12 erage for all health insurance plans pursuant to the  
13 amendments made by this Act. Such minimum year-  
14 ly coverage shall apply to an individual during any  
15 period when the individual is covered under the plan  
16 and for as long as deemed medically necessary. The  
17 Secretary may establish age-specific minimum levels  
18 of coverage and periodically update these levels  
19 based on a standard cost of living index, the actual  
20 cost of treatment, and other appropriate measures  
21 as determined by the Secretary.

22 (2) **NO PREEMPTION.**—The minimum yearly  
23 coverage determined by the Secretary under para-  
24 graph (1) shall not preempt any State standards

- 1 that require a higher minimum yearly coverage level
- 2 for the same services and benefits.

